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Attorney's Docket No. TRIPEP.23AUS2

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DECLARATION - USA PATENT APPLICATION

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As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled VACCINES CONTAINING RIBAVIRIN AND METHODS OF USE THEREOF, the specification of which was filed on August 15, 2001 as Application Serial No. 09/929,955 and was amended on .

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

I hereby claim the benefit under Title 35, United States Codes § 119(e) of any United States provisional applications listed below.

Application No.: 60/225,767

Filing Date: August 17, 2000

Application No.: 60/229,175

Filing Date: August 29, 2000

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application

Application No.: 09/705,547

Filing Date: 11/03/00

Status: Pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

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**VACCINES CONTAINING RIBAVIRIN
AND METHODS OF USE THEREOF**

5 **CROSS-REFERENCE TO RELATED APPLICATIONS**

This application claims priority to a U.S. Provisional Patent Applications Nos. 60/225,767 and 60/229,175, filed August 17, 2000 and August 29, 2000, respectively, and ~~U.S. Patent Application number 09/705,547, filed November 3, 2000,~~ all of which are hereby expressly incorporated by reference in their entireties.

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FIELD OF THE INVENTION

The present invention relates to compositions and methods for enhancing the effect of vaccines in animals, such as domestic, sport, or pet species, and humans. More particularly, preferred embodiments concern the use of ribavirin as an adjuvant and compositions having ribavirin and an antigen.

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BACKGROUND OF THE INVENTION

The use of vaccines to prevent disease in humans, farm livestock, sports animals, and household pets is a common practice. Frequently, however, the antigen used in a vaccine is not sufficiently immunogenic to raise the antibody titre to levels that are sufficient to provide protection against subsequent challenge or to maintain the potential for mounting these levels over extended time periods. Further, many vaccines are altogether deficient in inducing cell-mediated immunity, which is a primary immune defense against bacterial and viral infection. A considerable amount of research is currently focussed on the development of more potent vaccines and ways to enhance the immunogenicity of antigen-containing preparations. (See e.g., U.S. Pat. Nos. 6,056,961; 6,060,068; 6,063,380; and Li et al., *Science* 288:2219-2222 (2000)).

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Notorious among such "weak" vaccines are hepatitis B vaccines. For example, recombinant vaccines against hepatitis B virus such as Genhevacb (Pasteur Merieux Serums et Vaccines, 58, Avenue Leclerc 69007 Lyon, France), Engerixb (Smith, Kline and Symbol French), and Recombivaxhb (Merck, Sharp, and Dhome) are effective only

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Appl. No. : 09/929,955
Filed : August 15, 2001

31. (Previously presented) A method of making an immunogenic composition comprising:

providing ribavirin;
providing a nucleic acid that encodes a hepatitis antigen; and
combining said ribavirin and said nucleic acid to formulate said immunogenic composition.

32. (Previously presented) A method of making an immunogenic composition comprising:

providing ribavirin;
providing a nucleic acid that encodes a hepatitis C antigen; and
combining said ribavirin and said nucleic acid to formulate said immunogenic composition.

33. (Previously presented) A method of making an immunogenic composition comprising:

providing ribavirin;
providing a nucleic acid, that encodes a hepatitis C antigen comprising NS3; and
combining said ribavirin and said nucleic acid to formulate said immunogenic composition.

34. (Previously presented) A method of making an immunogenic composition comprising:

providing ribavirin;
providing a nucleic acid that encodes a hepatitis C antigen comprising NS4A; and
combining said ribavirin and said nucleic acid to formulate said immunogenic composition.

35. (New) The immunogenic composition of Claim 21, wherein said viral antigen encodes a peptide comprising the sequence of SEQ ID NO:17.

36. (New) The immunogenic composition of Claim 21, wherein said viral antigen encodes a peptide comprising an antigenic fragment of the sequence of SEQ. ID NO. 1.